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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,543	11/12/2003	Linda S. Powers	13368.0001 (DIV. III)	6900

7590 12/16/2004
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,543	POWERS ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Currently, claims 1-3 are pending and under consideration.
2. The numbering of the originally filed claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 73-75 have been renumbered, respectively, as claims 1-3.

Information Disclosure Statement

3. The information disclosure statement filed on November 12, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

While it is noted that the IDS filed in the present application appears to be a duplicate of the IDS filed on November 1, 2001 in the parent application (09/999,159) the present IDS does not comply with the requirements of 37 CFR 1.98 (d), which states as follows:

(d) A copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless:

(1) The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C.120; and

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(2) The information disclosure statement submitted in the earlier application complies with paragraphs (a) through (c) of this section.

There is no identification in the present IDS of the earlier application.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: It is suggested that the specification be amended to describe the claimed methods (e.g. by amending the specification to include the introductory language - "In one embodiment this application is directed to" - followed by the language of claim 1.

Appropriate correction is required.

Claim Objections

5. Claim 1 is objected to because of the following informalities: a comma should be inserted between the terms "discharge" and "and" in line 6 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. Claim 1 is treated as representative. This claim describes a method for the identification of a protein. The method comprises a first step of “exposing the solution containing microorganisms to conditions resulting in the rupture of the microorganisms.” It is not clear what solution is being referred to, as there is no antecedent basis in the claim for “the solution containing microorganisms.” It is suggested that the “the” in line 2 of the claim be replaced with an - - a- -.

Clarification is required.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is treated as representative. This claim describes a method for the identification of a protein. The method comprises a step (b) of “exposing a solution containing the protein analyte” to a ligand, and a step (c) and (d) which describe steps of separating and interrogating for an “analyte.” It is unclear if the “protein analyte” of step (b), and the “analyte” of steps (c) and (d), is the same as the protein identified in the claim preamble. It is suggested that the Applicant amend the claim such that 1) the antecedent basis for the term “the protein analyte” is made clear, and 2) compounds identified in the claims are referred to through consistent terminology throughout the claims.

Clarification is required.

9. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. Claim 1 is treated as representative. This claim describes a method for the identification of a protein. The method is described as including a first step of "exposing the solution containing microorganisms to conditions resulting in the rupture of the microorganism" and a second step of "exposing a solution containing the protein analyte to a ligand specific for the analyte of interest." The solution containing the microorganisms will be referred to as the first solution, and the solution containing the protein will be referred to as the second solution.

It appears from the claim that each of these steps is referring to the manipulation of a separate solution. However, as no other steps in the claim involve the use of the first solution. It is unclear 1) what the association is between the claimed method and the first solution, and 2) if this first solution is intended to be the same as (or a precursor to) the second solution.

Clarification is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection. In the Preliminary Amendment filed on November 12, 2003, the Applicant amended claim 1 to allow for the rupture of the microorganisms in the solution of subpart (a) through plasma discharge. However, there does not appear to be written

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description support for this limitation in the application as filed. The amendment of the claim to include this subject matter is therefore rejected as New Matter. The Applicant is requested to point out where support for this limitation may be found in the application as filed, or to cancel the rejected subject matter from the claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al. (WO 98/49557) and further in view of the teachings of Waskiewicz et al. (EP 0 286 434) and Trudil (U.S. 6,395,504). These claims read on methods for the detection of a protein comprising exposing a solution comprising a protein to a substrate comprising a ligand to the protein, separating the bound ligand from the non-binding components of the solution, and detecting the presence of the protein on the substrate surface. For the purposes of this rejection, the claims are interpreted to additionally require that the analyte bind to a ligand tethered to the substrate by a tether of at least 40 Å in length, and that the protein solution is a solution resulting from the lysis or rupture of microorganisms in a solution containing such (i.e. that the protein solution of (b) is the result of the lysis or rupturing of the microorganisms in (a)).

Powers teaches a method for the detection of analytes, including proteins, by querying a solution with a ligand tethered to a substrate. See e.g., pages 8-9. The reference additionally

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teaches that the proteins so identified may be detected through the use of intrinsic fluorescence. See e.g., pages 25-26, and 30-32. Thus, the reference teaches methods of detecting proteins through capture by a ligand tethered to a substrate. The reference does not however, teach the use of tether of 40 Å in length, or the lysis or rupture of a microbial cell.

However, although the Powers reference does not teach the claimed tether length for joining the ligand to the substrate, such limitations are obvious as one skilled in the art would know to maximize the effectiveness of such an assay by adjusting the length of the tether to account for the size of the target analyte. See e.g. U.S. Patent 6,124,102, column 18, lines 19-64 (teaching that tether length for attaching a compound to a substrate “are selected for optimum length” for improved binding between the ligand and receptor.”) Thus, it would have been obvious optimization to those in the art to have used tethers of the disclosed length to attach the ligand to the substrate for use in the method of Powers.

Additionally, each of Trudil and Waskiewicz teach that the presence of bacteria may be indirectly determined through the detection of bacterial proteins or constituents. See e.g., Waskiewicz, abstract; and Trudil (column 12, lines 11-17). Because these proteins teach that the presence of bacteria may be determined by the detection of bacterial proteins, and because the Powers reference teaches that the method disclosed therein may be used to detect either bacteria or proteins, it would have been obvious to those in the art to use the method of Powers to detect the bacterial proteins as suggested by Waskiewicz and Trudil. The teachings of these references therefore render obvious the claimed methods.

Double Patenting

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14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 21, 23, and 30 of U.S. Patent No. 6,780,602 in view of Trudil, and Waskiewicz as described above. The claims of the patent read on methods for the detection of biological analytes through methods comprising steps (b)-(d) of the present claims. The claims of the patent do not teach step (a) of the currently claimed method, although the claims of the patent are generic to the claims of the present application.

However, the additional teachings of Trudil, and Waskiewicz as described above render obvious the use of a protein solution achieved through lysis or rupture of a microorganism for the detection of a protein therein. Thus, the claims of the present application represent an obvious variation to the claims of the patent.

16. Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-23, and 26 of copending Application No. 10/706,547 or over claims 38, 39, 41, and 47 of copending Application NO. 10/706,542 in view of Powers, Trudil, and Waskiewicz as described above. The claims of the

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compending applications read on methods of detecting biological analytes, including proteins, through a method comprising steps substantially identical to steps (b)-(d) of the method claimed in the present application. The claims of the compending applications do not teach the lysis or rupture of a microorganism to make the protein solution. However, in view of the teachings of Trudil and Waskiewicz as described above, such a step would have been an obvious variation of the method of the compending application.

It is also noted that the claims of the compending applications require that the tether be at least six Å in length. This limitation is generic to the requirement of at least forty Å in the present application. Additionally, the currently claimed tether length would have been an obvious variation of the method of the compending application for the same reasons as indicated above with respect to the Powers et al. reference.

This is a provisional obviousness-type double patenting rejection.

Conclusion

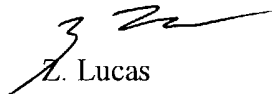
17. No claims are allowed.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 12/13/04
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